# Pharmacotherapy - Procedural Anticoagulants

## *Washington Convention Center, Lower Level, Hall A*

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### TCT-460

**Bivalirudin versus heparin during percutaneous coronary intervention: a meta-analysis of randomized trials**

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**Background:** Current recommendation on the use of bivalirudin in patients undergoing percutaneous coronary intervention (PCI) are mostly based on trials comparing bivalirudin versus heparin plus planned glycoprotein IIb/IIIa inhibitor (GPI). Whether bivalirudin is also superior to heparin alone is still not fully established. This meta-analysis investigates the efficacy and safety of bivalirudin versus heparin in patients treated with PCI and provisional or bailout GPI use.
**Methods:** Scientific databases and websites were searched. The primary efficacy and safety outcomes were the 30-day incidence of death and major bleeding, respectively. The secondary outcomes were the 30-day incidence of myocardial infarction (MI), definite stent thrombosis (ST) and urgent target vessel revascularization (TVR). Odds ratio (OR) and 95% confidence interval [95% CI] served as summary statistics.
**Results:** A total of 18,065 PCI-patients randomized to bivalirudin (n= 9,033) versus heparin (n= 9,032) were studied. At 30 days, bivalirudin versus heparin shows comparable risk of death (1.09 [0.83-1.41], p= 0.54), lower risk of major bleeding (0.57 [0.40-0.80], p= 0.001), higher risk of definite ST (2.09 [1.26-3.47], p= 0.005), comparable risk of MI (1.10 [0.83-1.46], p= 0.50) with a trend towards a higher risk of urgent TVR (1.37 [0.96–1.96], p= 0.08). In particular, the risk of acute ST (within 24 hours) is increased by bivalirudin (3.48 [1.66-7.28], p< 0.001).
**Conclusions:** In patients treated with PCI, bivalirudin versus heparin does not reduce mortality. The lower risk of major bleeding is achieved at the expense of a higher risk of acute ST.

### TCT-461

**Bivalirudin Versus Unfractionated Heparin in Percutaneous Coronary Intervention for Stable Angina: A Randomized Clinical Trial (STATUS-PCI)**

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**Background:** Few direct comparisons between unfractionated heparin (UFH) monotherapy vs. bivalirudin (Angiomax, The Medicine's Company Inc., Parsippany, NJ) for percutaneous coronary intervention (PCI) in patients with stable angina exists in the modern era of dual anti-platelet therapy.
**Methods:** STATUS-PCI is a prospective, investigator initiated, single-center, single-blinded, randomized 1:1 trial of UFH vs. bivalirudin in patients with stable angina or silent ischemia on non-invasive stress testing undergoing PCI of 1 or more >70% coronary stenosis. The primary endpoint of the study was comprised of major and minor bleeding events (defined by the REPLACE-2 trial definition) during the index hospitalization and up to 30 days. Secondary endpoints included major adverse cardiac events (MACE) comprising all-cause mortality, myocardial infarction (MI), ischemia driven target vessel revascularization (TVR), and cerebral vascular accident (CVA) and net adverse cardiac events (NACE), defined as a composite of MACE and any bleeding event at 30 days. Based on chi-square testing with the significance level of 0.05 and a power of 0.80, 388 patients in each group (with continuity correction) are required to show a 50% relative decrease in bleeding in the bivalirudin arm, assuming a 12% rate of bleeding in the control arm (i.e. UFH).
**Results:** The study was halted prematurely for futility by the data safety monitoring board after enrollment of 260 patients. There were no significant differences in baseline characteristics between the 2 groups. Radial access was used in 28.5% vs. 23.4% (p=0.348) and closure devices were used in 50.8% vs. 55.6% (p=0.447) in the UFH and bivalirudin groups, respectively. The primary endpoint occurred in 22 patients (8.5%) without a significant difference between the groups (11 [8.9%] vs. 11 [8.0%], p=0.808). MACE at 30 days occurred in 0 vs. 3 (2.2%) [p=0.10] and NACE in 11 (8.9%) vs. 14 (10.2%) [p=0.71] patients in the UFH and bivalirudin groups, respectively.
**Conclusions:** Among patients with stable ischemic heart disease undergoing PCI on dual anti-platelet therapy, there was no significant difference between UFH and bivalirudin with respect to bleeding events or MACE at 30 days.

### TCT-462

**Heparin versus Bivalirudin in patients undergoing Percutaneous Coronary Intervention**

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**Background:** Anti-platelet and anti-coagulant adjunctive therapies are associated with an increased risk of major bleeding that adversely impacts on clinical outcomes. Objective: To retrospectively assess the in hospital MACE and major bleeding in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention(PCI) received either unfractionated heparin (UFH) or Bivalirudin.
**Methods:** Consecutive patients undergoing PCI for ACS at Fremantle Hospital from August 2008 to December 2013 were identified. All patients were pre-treated with dual antiplatelet therapy. Patients received intravenous UFH (50-100IU/kg) to achieve activated coagulation time 250 to 300s or Bivalirudin (bolus 0.75 mg/kg and Infusion 1.75 mg/kg/hr). Adjunctive glycoprotein IIbIIIa was given at the discretion of the operator. In-hospital MACE and bleeding events were identified from systematic review of case notes after hospital discharge and from PCI database.
**Results:** 3371 patients were identified, 1741 received UFH and 1631 received Bivalirudin. Mean age was 62.3 years in both groups (p=0.575). Female gender was 24% vs. 26% (p=0.10) , current smoking 66% vs. 70% (p=0.53, and diabetes 25% vs. 26% (p=0.62) in UFH vs. Bivalirudin groups. 85% of patients received Clopidogrel, 8% Ticagrelor and 4% Prasugrel in both groups(p= ns). In UFH vs. Bivalirudin groups STEMI presentation was 28% vs. 19%, NSTEMI/USA 51% vs. 58% and elective 19% vs. 23% respectively. Trans-femoral access was used in 93% vs. 92% (p=0.41). More patients received GPIIbIIIa antagonists in the UFH group (30.2% vs. 3.4%; p< 0.001). Pre-discharge stent thrombosis were noted in 1.0% with UFH vs. 0.5% with Bivalirudin(p=0.20). The incidence of in hospital MACE was similar and the incidence of BARC 1(Bleeding Academic Research consortium) was1.8% in UFH group vs. 1.1% bivalirudin group. BARC2 bleeding was 1.5% Bivalirudin vs. UFH 2.1%(p=0.228). BARC 5 major bleeding was 0.0% in both groups.
**Conclusions:** In this PCI cohort, UFH compared with Bivalirudin was not associated with a high incidence of in hospital MACE and major bleeding despite a significantly higher rate of GPIIbIIIa antagonist treatment in the UFH group.

### TCT-463

**Does Routine Post-Procedural Anticoagulation Reduce Acute Stent Thrombosis after Bivalirudin Anticoagulation During Primary PCI? The HORIZONS-AMI Trial**

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**Background:** The rate of acute (≤24 hours) stent thrombosis (ST) is increased with bivalirudin anticoagulation (AC) during primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI) compared to heparin plus the routine use of a glycoprotein IIb/IIIa inhibitor. Prior studies suggest that pre-PCI unfractionated heparin (UFH) may protect against acute ST, presumably due to its longer half-life. In this regard, whether the routine use of post-PCI AC is able to prevent ST in this setting is unknown. We therefore evaluated outcomes after routine AC prophylaxis following primary PCI in bivalirudin-treated pts from the HORIZONS-AMI trial.
**Methods:** 1,445 pts who received bivalirudin during primary PCI were grouped according to use of pre-PCI UFH, post-PCI AC for routine prophylaxis, both, or neither. Acute and 30-day rates of definite or probable ST were assessed using propensity-adjusted multivariable analysis.
**Results:** 948 pts (65.6%) received pre-PCI UFH, 436 (30.2%) received post-PCI AC for routine prophylaxis (for median 4.0 days), and 386 (26.7%) received neither. 623 pts (43.1%) received only pre-procedural UFH and 111 (7.7%) received only post-PCI AC for routine prophylaxis. ST occurred in 13 pts (0.9%) within the first 24 hours post PCI and in 27 pts (1.9%) within 30 days. By multivariate analysis, post-PCI AC for routine prophylaxis was not associated with reduced acute or 30-day ST, regardless of whether or not pts also received pre-PCI UFH (Table).
**Conclusions:** In this large-scale study, post-PCI AC for routine prophylaxis following bivalirudin monotherapy during primary PCI was not associated with a reduction in acute or 30-day ST.